510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR §807.92

K012186

DEC 0 7 2001

1. Submitter's Name: **Master & Frank Enterprise Co., Ltd.**

Address: 15F-1, No. 57, Sec. 2, Tun Hea S. Rd. Taipei, Taiwan, R.O.C.

Phone: 886-2-2325-5066

Fax: 886-2-2702-6577

Contact: Mr. Frank Wu (General Manager)

2. Device Name

Trade Name: Master & Frank Surgical Gowns(Sterile)

Common Name: Sterile Surgical Gowns

Classification name: GOWN , SURGICAL

3. Classification: Class II

4. Predicate Device: **Medline Disposable Surgical Drapes & Gowns (K964142)**

5. Device Description: **Master & Frank Surgical Gowns (Sterile),** is manufactured from non-woven fabric. This surgical Gown is supplied sterile and for single use only.

6. Intended Use: **Master & Frank Surgical Gowns (Sterile)** is a single use article of surgical apparel worn by operating room personnel during surgical procedures to protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material.

7. Performance Summary: In terms of Physical specification -- ASTM D1424 , ASTM D5034 & NFPA Flammability standards----etc, Biological specification ISO 10993 series & Sterilization Specification ISO 11137 & ISO 11607-1 , the device are designed to meet applicable standards..

8. Conclusions:

The **Master & Frank Surgical Gowns (Sterile)** have the same intended use and similar technological characteristics as the **Medline Disposable Surgical Drapes & Gowns (K964142).** Moreover, bench testing contained in this submission demonstrate that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the **Master & Frank Surgical Gowns (Sterile)** is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 7 2001

Master & Frank Enterprise Company Limited
C/O Ms. Jennifer Reich
Harvest Consulting, Incorporated
3892 South America West Trail
Flagstaff, Arizona 86001

Re: K012186
Trade/Device Name: Master & Frank Surgical Gowns (Sterile)
Regulation Number: 878.4040
Regulation Name: Sterile Surgical Gowns
Regulatory Class: II
Product Code: FYA
Dated: November 20, 2001
Received: November 23, 2001

Dear Ms. Reich:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510 (k) NUMBER (IF KNOWN): K012186

DEVICE NAME: Mater & Frank surgical Gowns (Sterile)

INDICATIONS FOR USE:

Master & Frank Surgical Gowns (Sterile) are single use article of surgical apparel that is intended to be worn by operating room personnel during surgical procedures to help protect both the surgical patient and the operating room personnel from transfer of microorganisms, body fluids, and particulate material.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Prescription Use _____ OR Over-The-Counter V
(Per 21 CFR 801.109) (Optional Format)

Chun S. Lin
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K012186